

on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the enrollee's response will not be counted toward the adjudication deadline.

§ 423.2120 Filing briefs with the MAC.

Upon request, the MAC will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in § 423.2100. The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor either participates, or decides not to participate in MAC review.

§ 423.2122 What evidence may be submitted to the MAC.

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC will consider the evidence contained in the record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. If the hearing decision decides a new issue that the enrollee was not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(3) The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after

a coverage determination is made. The MAC will remand a case to the Part D IRE if the MAC determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination considered.

(b) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The MAC may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or a portion of the subpoena.

(2) Upon notice to the MAC that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena, tolling the time period for the MAC to issue a final action or remand a case in response to a request for review for 15 calendar days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement.* (1) If the MAC determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the MAC to issue a final action or remand a case in response to a request for review is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(3) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or other person or entity subject to the subpoena.

(4) The MAC must promptly mail a copy of the notice and related documents to the enrollee or other person or entity subject to the subpoena, and to any other affected person.

§ 423.2124 Oral argument.

An enrollee may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it informs the enrollee of the time and place of the oral argument at least 10 calendar days before the scheduled date or, in the case of an expedited review, at least 2 calendar days before the scheduled date.

(c) In case of a previously unrepresented enrollee, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in the oral argument.

§ 423.2126 Case remanded by the MAC.

(a) *When the MAC may remand a case to the ALJ.* (1) The MAC may remand a case in which additional evidence is needed or additional action by the ALJ is required. The MAC will designate in

its remand order whether the ALJ will issue a decision or a recommended decision on remand.

(2) *Action by ALJ on remand.* The ALJ will take any action that is ordered by the MAC and may take any additional action that is not inconsistent with the MAC's remand order.

(3) *Notice when case is returned with a recommended decision.* When the ALJ sends a case to the MAC with a recommended decision, a notice is mailed to the enrollee at his or her last known address. The notice tells the enrollee that the case was sent to the MAC, explains the rules for filing briefs or other written statements with the MAC, and includes a copy of the recommended decision.

(4) *Filing briefs with the MAC when ALJ issues recommended decision.* (i) An enrollee may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 calendar days of the date on the recommended decision or with the request for review for expedited appeals. An enrollee may ask the MAC for additional time to file a brief or written statement. The MAC will extend this period, as appropriate, if the enrollee shows that he or she has good cause for requesting the extension.

(ii) All other rules for filing briefs with and obtaining evidence from the MAC follow the procedures explained in this subpart.

(5) *Procedures before the MAC.* (i) The MAC, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(ii) If the MAC determines that more evidence is required, it may again remand the case to an ALJ for further inquiry into the issues, rehearing, receipt of evidence, and another decision or recommended decision. However, if the MAC decides that it can get the additional evidence more quickly, it will take appropriate action.

(b) *When the MAC must remand a case to the Part D IRE.* The MAC will remand a case to the appropriate Part D IRE if the MAC determines that the enrollee wishes evidence on his or her change in condition after the coverage